



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 21, 2020

Tony Herber
Agent
Best Sanitizers, Inc.
PO Box 1360
Penn Valley, CA 95946

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: ALPET D2
EPA Registration Number: 73232-1
Application Date: 03/05/2020
Decision Number: 560783

Dear Mr. Herber:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

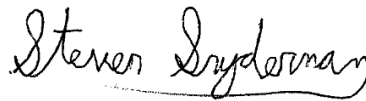
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Norovirus (Feline calicivirus as surrogate) ATCC VR-782 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive, flowing style.

Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

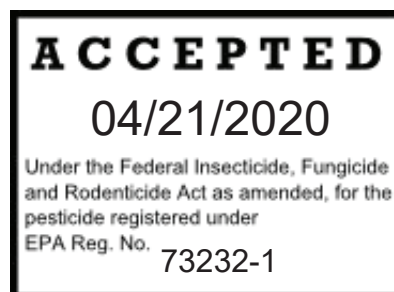
Enclosure: stamped label

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

ALPET D2



{logo color may vary}



[READY TO USE]

[FAST ACTING¹]

[QUICK DRYING]

[HIGHLY EVAPORATIVE]

[IDEAL FOR WATER SENSITIVE] [ENVIRONMENTS or AREAS] [AND LOW MOISTURE ENVIRONMENTS]

[IDEAL FOR WATER SENSITIVE EQUIPMENT]

[NO-RINSE] [REQUIRED]

[FOOD CONTACT SURFACE SANITIZER WITHOUT RINSE]

Kills 99.9% of bacteria on non-food contact surfaces [in 10 seconds]

Kills 99.999% of bacteria on food contact surfaces [in 60 seconds]

Sanitizes food contact surfaces in 60 seconds

Sanitizes non-food contact surfaces in 10 seconds

Kills 99.9% of bacteria in 10 seconds¹

Kills 99.999% of bacteria in 60 seconds²

**CLEANS AND SANITIZES FOOD CONTACT AND NON-FOOD CONTACT SURFACES
DISINFECTANT / TUBERCULOCIDAL / VIRUCIDAL* / FUNGICIDAL**

ACTIVE INGREDIENTS:

Isopropyl Alcohol 58.6000 %

Octyl Decyl Dimethyl Ammonium Chloride 0.0075 %

Didecyl Dimethyl Ammonium Chloride 0.0045 %

Diocetyl Dimethyl Ammonium Chloride 0.0030 %

OTHER INGREDIENTS: 41.3850 %

TOTAL 100.0000 %

[Depending on container size, the following statement may appear on the final label] - Not for individual sale

KEEP OUT OF REACH OF CHILDREN WARNING

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	

¹ Non-food Contact Surfaces

² Food Contact Surfaces

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For non-emergency product information, contact 1-888-225-3267 between 8:00 A.M. and 4:30 P.M. Pacific Time. For 24/7 emergency response regarding this product, contact CHEMTREC at 1-800-424-9300

[Depending on container size, the following statements may appear on the final label] See side panel for first aid and precautionary statements. See accompanying pamphlet for directions for use and additional precautionary statements.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear, such as safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

**Manufactured [For:] [By:]
BEST SANITIZERS, INC.**



{logo color may vary}

**P.O. BOX 1360
PENN VALLEY, CA 95946
[phone] 888-225-3267
E.P.A. Reg. No. 73232-1
E.P.A. Est. No. 073232-KY-001**

Net Contents: Lot No. (Expiry Date)

[Note to Reviewer: For containers of 5 gallons or more, the following Environmental Hazards language will appear on the final product label]

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

CLEANING

Alpet D2 [This product] is recommended for use as a cleaner on hard non-porous food contact and non-food contact surfaces such as [conveyors, belts, driers, blanchers, roasters, ovens, refrigerators, freezers, chillers, hoppers, extruders, fillers, fill heads, mixers, blenders, [meat] [cheese] [deli] slicers, saws, snippers, choppers, dicers, grinders, huskers, peelers, presses, evaporators, pasteurizers, graders, sizing cups, labelers, packaging equipment, case packers, pipelines, bins, crates, containers, tubs, totes, carts, buggies, tanks, vats, walls, floors, doors, door

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

handles, tables, counters tops, benches, chairs, drip pans, troughs, drains, racks, forklifts, tires, pallet jacks, pallets, timeclocks, hand hygiene dispensers, hard hats, aprons, gloves, boots, tools, tool boxes, knives, utensils, thermometers, control panels, proximity switches, thermostats, motors, pumps and scales]. Remove gross food particles and soil from the surface. Apply this product [Alpet D2] without dilution to the surface and wipe clean. Allow to dry. A water rinse after applying the product is permissible in wet environments if necessary to aid in the cleaning process.

SANITIZING NON-FOOD CONTACT SURFACES

This product [Alpet D2] is recommended as a sanitizer for use on non-food contact surfaces such as [conveyors, floors, walls, tables, chairs, benches, cabinets, troughs, carts, baskets, forklifts, tires, pallet jacks, plastic pallets, telephones, plastic surfaces, glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces] and other related hard, non-porous surfaces. Preclean surfaces prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe, sponge, or by total immersion and ensure exposure to sanitizer for at least 10 seconds. Allow surfaces to air dry. This product [Alpet D2] is effective against *Staphylococcus aureus* [(ATCC 6538)] and *Klebsiella pneumoniae* [(ATCC 4352)].

FOOTWEAR SANITIZER

This product [Alpet D2] is recommended as a sanitizer for use on outside surfaces of non-porous waterproof footwear such as boots, and work boots. Preclean footwear prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe or total immersion to ensure exposure to sanitizer for at least 10 seconds. Allow surfaces to air dry.

SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD NON-POROUS FOOD CONTACT SURFACES:

This product is recommended for use as a sanitizer on food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard non-porous food contact surfaces.

Preclean surfaces prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe, sponge, or by total immersion. Surfaces must be thoroughly wetted. Treated surfaces must remain wet for 60 seconds [1 minute].

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by sponge, wipe, brush or coarse spray. Surfaces must remain wet for at least one minute followed by adequate draining and air-drying. Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion with this product. Always use fresh solution for this purpose.

Alpet D2 [This product][kills 99.999% of the following bacteria:] [is an effective sanitizer against] *Staphylococcus aureus* [(ATCC 6538)], *Escherichia coli* [(ATCC 11229)], *Escherichia coli* O157:H7 [(ATCC 35150)], *Pseudomonas aeruginosa* [(ATCC 15442)], *Salmonella enterica* (formerly *typhimurium*) [(ATCC 10708)], *Listeria monocytogenes* (ATCC 19117), *Enterobacter sakazakii* [(ATCC 29544)], *Klebsiella pneumoniae* [(ATCC 4352)] and *Vibrio cholerae* [(ATCC 14035)]- on hard non-porous food contact surfaces. Treated surfaces must remain wet for 60 seconds [1 minute]. Allow to air dry.

SANITIZING NON-POROUS WATERPROOF GLOVES

This product [Alpet D2] is recommended as a sanitizer for use on non-porous and waterproof gloves. Preclean gloves prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe or total immersion to ensure exposure to sanitizer for at least 60 [1 minute] seconds. Allow surfaces to air dry. Do not rinse.

Wisconsin State Board of Health Directions for Eating Establishments

1. Scrape and pre-wash utensils and glasses whenever possible.
 2. Wash with a good detergent or compatible cleaner.
 3. Rinse with potable water.
 4. Sanitize in an undiluted solution of this product. Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
 5. Place sanitized utensils on a rack or drain board to air-dry.
 6. Prepare a fresh sanitizing solution at least daily or when visibly soiled or diluted.
- NOTE:** A clean potable water rinse following sanitization is not permitted under HFS 196, Ref. Appendix 7-204.11 of the Wisconsin Administrative Code.

DISINFECTION

This product is recommended for use as a disinfectant on inanimate, precleaned, hard, non-porous surfaces such as chairs, countertops, drawer pulls, carts, baskets, tables, cabinets, telephones, plastic surfaces, glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces and other related hard surfaces in hospitals, operating rooms, medical clinics, nursing homes, laboratories, schools, day care centers, funeral homes.

Preclean surfaces prior to disinfecting. This product may be used to preclean. To disinfect, apply with a sponge, wipe, mechanical sprayer, or by total immersion. When applied with a mechanical spray, spray should be coarse. Surfaces must be sprayed until thoroughly wetted. Treated surfaces must remain wet for 5 minutes.

[Bacteria:]

This product [kills 99.9% of the following bacteria] {-or-} is an effective disinfectant according to the AOAC Use-Dilution Test method on hard inanimate surfaces against: *Staphylococcus aureus* MRSA[(ATCC 33592)], *Staphylococcus aureus* [(ATCC 6538)], *Enterococcus faecium* VRE [(ATCC 51575)] *Escherichia coli* O157:H7 [(ATCC 35150)] *Pseudomonas aeruginosa* [(ATCC 15442)], *Listeria monocytogenes* [(ATCC 19117)], and *Salmonella enterica* (formerly *choleraesuis*) [(ATCC 10708)].

[Viruses:]

This product [Alpet D2] is an effective virucidal disinfectant against the following viruses on hard non-porous surfaces: Norovirus (Feline Calicivirus as surrogate) [(ATCC VR-782)], Influenza A H1N1 [(ATCC/IRR FR-371)], Hepatitis B Virus, and Human Immunodeficiency Virus Type 1 (HIV-1)

[Fungi]

This product [Alpet D2] is an effective fungicidal disinfectant against [the fungus] *Trichophyton mentagrophytes* [(ATCC 9533)] on hard non-porous environmental surfaces. [Apply product with a sponge, wipe, or mechanical sprayer, or by total immersion. Treated surfaces must remain wet for 5 minutes.]

TUBERCULOCIDAL ACTIVITY – This product exhibits disinfectant efficacy against *Mycobacterium bovis* (BCG) in 5 minutes at 20°C when used as directed on previously cleaned hard non-porous inanimate surfaces.

***KILLS HIV-1 AND HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS**

PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (e.g. hospitals, nursing homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) AND HBV ON SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS

Personal Protection: Wear disposable latex gloves, protective gown, face mask and eye covering, as appropriate, when handling items soiled with blood or body fluids.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

Contact Time: Leave surfaces wet for five minutes. For other organisms identified above, allow surface to remain wet for 5 minutes

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

{The following statement will appear on container labels only if healthcare use sites are listed on the label}

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. Alpet D2 [This product] may be used to clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

{Emerging Viral Pathogens}

{This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

The statements shall be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.}

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Norovirus (Feline Calicivirus as surrogate) [(ATCC VR-782)]
Large, non-enveloped virus	Norovirus (Feline Calicivirus as surrogate) [(ATCC VR-782)]

This product [-or- Product Name] has demonstrated effectiveness against viruses similar to {Insert name of emerging virus} on hard, nonporous surfaces. Therefore, this product [-or-Product Name] can be used against {Insert name of emerging virus} when used in accordance with the directions for use against Norovirus on hard, nonporous surfaces. Refer to the CDC -or- OIE website at {Insert pathogen-specific website address} for additional information.

{Insert name of illness/outbreak} is caused by {Insert name of emerging virus}. This product [-or-Insert Name] kills similar viruses and therefore can be used against {Insert name of emerging virus} when used in accordance with the directions for use against Norovirus on hard, nonporous surfaces. Refer to the {CDC -or- OIE} website at {Insert pathogen-specific website address} for additional information.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE-Open dumping is prohibited. Store only in the original container. Keep this product under locked storage sufficient to make it inaccessible to children or people unfamiliar with its proper use. Store in a cool dry area away from flames, sparks or other sources of heat or ignition. If ignited, use dry chemical or CO₂ extinguisher. If a large quantity is spilled, dilute with water and mop or wipe dry.

PESTICIDE DISPOSAL-Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL- Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local regulations.

LIMITED WARRANTY AND DISCLAIMER

NOTICE: Best Sanitizers, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions For Use. Buyer assumes all risks of use and handling which is a variance in any way with the directions herein. To the extent consistent with applicable law, Best Sanitizers, Inc. makes no other express or implied warranty of fitness or merchantability. To the extent consistent with applicable law, in no case shall Best Sanitizers, Inc. or the seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. Best Sanitizers, Inc. and Seller offer this product and the Buyer and user accept it, subject to the foregoing **Limited Warranty and Disclaimer** which may be varied only by agreement in writing signed by a duly authorized representative of Best Sanitizers, Inc.



[NSF logo (black)]



or [NSF logo (blue)]



[Kosher / Pareve symbol]



[Halal Symbol]

{Depending on container size, labeling may contain one of the following part numbers:}

REORDER: SS10001

REORDER: SS10002

REORDER: SS10002-BSS

For use with ADB0001 HACCP Defender™

and ADB0002 HACCP SmartStep™

Footwear Sanitizing Stations

REORDER: SS10003

{used for multi-panel labels}

Peel Here

Continued on inside label